

BDH INDUSTRIES LIMITED.

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CIN : L24100MH1990PLC059299


Certificate No.
T/119/619
CERTIFICATE OF ANALYSIS

The Drugs and Cosmetics Act 1940 and the rules there under

Name of the Manufacturer : **BDH INDUSTRIES LIMITED**
 Name of the Product : **KETOCONAZOLE TABLETS 200 mg**
 MFG Lic No. : 608 Mfg Dt. : 06/2019
 Sample received as : Final Product Exp Dt. : 05/2022
 Batch No. : 230619 Date of Receipt : 24/06/2019
 Quantity manufactured : 4,20,000 Tablets Date of Report : 27/06/2019
 Quantity for analysis : 5 X 10 Tablets (Blister pack)

RESULTS OF ANALYSIS**TABLETS**

TEST		OBSERVATION			LIMIT / SPECIFICATION	
Description		Almost white, circular, flat uncoated tablets with breakline on one side.			White to almost white, circular, flat uncoated tablets with breakline on one side.	
Average weight of tablet		0.3236 g			0.320 g ± 7.5%	
Uniformity of weight		Passes			± 7.5% of Avg.weight	
Maximum weight		0.334 g			0.3479 g	
Minimum weight		0.320 g			0.2993 g	
Diameter		9.56 mm			9.5 mm ± 0.6 mm	
Hardness		5.0 kg/cm ²			3.0 to 9.0 kg/cm ²	
Thickness		3.66 mm			3.7 ± 0.6 mm	
Friability		0.19%			Max. 1%	
Identification (TLC)		Complies			To comply USP	
Uniformity of dosage units (Acceptance value)		2.784			NMT 15	
		% of L. Amt. Released			Limits allowed	
Dissolution	Passes	100.38%	101.77%	101.42%	Min 80% within 30 mins	
		101.08%	103.15%	101.77%		
Name of the Ingredients assayed		Labelled amt per tablet	Obs. Amt. per tablet		% of L. Amt.	Limits allowed
Ketoconazole		200 mg	198.59 mg		99.30%	90% to 110%

RESULT: From the above tests, I certify that the sample complies with the prescribed standards of quality as per USP.

27/06/2019			
	MR. ARHMEET K	SURESH P.	MS. M V MHATRE
DATE	ANALYST	APPROVED CHEMIST	QC MANAGER

Doc. Ref.No. : BDH/QR/QC-FT (B)

Rev : 0 DATE : 01.03.08